

**REMARKS**

Pursuant to the present amendment, claim 38 has been amended. Claims 1-59 are pending in the present application. No new matter has been introduced by way of the present amendment. Reconsideration of the application is respectfully requested.

In the Office Action, claim 38 was rejected under 35 U.S.C. § 112 on the basis of a lack of antecedent basis for the claim. Pursuant to the present amendment, dependent claim 38 has been amended to depend from dependent claim 37. It is believed this cures the antecedent basis issue identified by the Examiner. Withdrawal of the rejection of claim 38 is respectfully requested.

As an initial matter, claims 12, 27, 29, 30, 39, 47 and 49 were indicated to be allowable if rewritten in independent form. While it is believed that these claims are certainly allowable, as set forth more fully below, it is believed that all pending claims are in condition for allowance in view of the art of record.

In the Office Action, claims 1-4, 6, 10, 13-19, 24, 25, 28, 31, 32, 37, 40, 41, 43, 46, 48, 51-55 and 57-58 were rejected under 35 U.S.C. § 102 as allegedly being anticipated by Chanet (U.S. Patent No. 6,588,301). Claims 5, 7, 9, 11, 18, 20-23, 26, 30, 33-36, 38, 42, 44, 45, 50, 56 and 59 were rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Chanet. Applicants respectfully traverse the Examiner's rejections.

As the Examiner well knows, an anticipating reference by definition must disclose every limitation of the rejected claim in the same relationship to one another as set forth in the claim. *In re Bond*, 15 U.S.P.Q.2d 1566, 1567 (Fed. Cir. 1990). To the extent the Examiner relies on principles of inherency in making the anticipation rejections in the Office Action, inherency requires that the asserted proposition necessarily flow from the disclosure. *In re Oelrich*, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981); *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1463-64 (Bd. Pat. App.

& Int. 1990); *Ex parte Skinner*, 2 U.S.P.Q.2d 1788, 1789 (Bd. Pat. App. & Int. 1987); *In re King*, 231 U.S.P.Q. 136, 138 (Fed. Cir. 1986). It is not enough that a reference could have, should have, or would have been used as the claimed invention. “The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *Oelrich*, at 326, quoting *Hansgirk v. Kemmer*, 40 U.S.P.Q. 665, 667 (C.C.P.A. 1939); *In re Rijckaert*, 28 U.S.P.Q.2d 1955, 1957 (Fed. Cir. 1993), quoting *Oelrich*, at 326; see also *Skinner*, at 1789. “Inherency ... may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *Skinner*, at 1789, citing *Oelrich*. Where anticipation is found through inherency, the Office’s burden of establishing *prima facie* anticipation includes the burden of providing “...some evidence or scientific reasoning to establish the reasonableness of the examiner’s belief that the functional limitation is an inherent characteristic of the prior art.” *Skinner* at 1789.

Moreover, to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant’s disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991); M.P.E.P. § 2142. Moreover, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974). If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988); M.P.E.P. § 2143.03.

With respect to alleged obviousness, there must be something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561 (Fed. Cir. 1986). In fact, the absence of a suggestion to combine is dispositive in an obviousness determination. *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573 (Fed. Cir. 1997). The mere fact that the prior art can be combined or modified does not make the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990); M.P.E.P. § 2143.01. The consistent criterion for determining obviousness is whether the prior art would have suggested to one of ordinary skill in the art that the process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art. Both the suggestion and the expectation of success must be founded in the prior art, not in the Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991; *In re O'Farrell*, 853 F.2d 894 (Fed. Cir. 1988); M.P.E.P. § 2142.

In rejecting pending claims, the Examiner took the position that the recitation that the sharpened tip of the fracture pin is adapted to penetrate subchondral bone is not a limitation of the claims in any patentable sense. More specifically, the Examiner held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform, and it does not constitute a limitation in any patentable sense. Office Action, p. 3 (citing *In re Hutchison*, 69 U.S.P.Q. 138). Applicants respectfully disagree with the Examiner on this issue.

Applicants respectfully submit that the Examiner's reliance on *Hutchison* is misapplied. The language in *Hutchison* regarding the "adapted to" language occurs in an introductory clause occurring prior to elements of the claims. *Hutchison* does not state categorically, that recitation "adapted to" does not constitute a positive limitation, but rather, that it does not constitute a

limitation in the context it was used in *Hutchison*, in the preamble. This assertion is supported by the statements of the Board of Patent Appeals and Interferences in *Ex Parte Robert-A. Ollar*, 1994 WL 1687107, Bd. Pat .App & Interf., 1994, which states:

“On the other hand, we are aware of support for a holding that ‘adapted to’ and ‘whereby’ clauses in claims further limit the claimed subject matter and should not be disregarded. For example, see *In re Venezia*, 530 F.2d 956, 958-59, 189 U.S.P.Q. 149, 151-52 (CCPA 1976). *Pac-Tec Inc. v. Amerace Corp.*, 903 F.2d 796, 801, 14 U.S.P.Q.2d 1871, 1876 (Fed. Cir. 1990) recognizes (emphasis added) that: ... by deleting the preamble and all limitations that include ‘adapted to,’ ‘whereby,’ and ‘thereby’ ... the claims are reduced to mere collections of parts.”

The use of “adapted to” language was specifically approved by the Board of Patent Appeals and Interferences in an appeal taken in the application that resulted in U.S. Patent No. 6,666,754. In the appeal of that case, the Board of Patent Appeals and Interferences did not sustain the Examiner’s rejection under 35 U.S.C. § 112 for the use of the terminology “adapted to” in the claims at issue in that case. Decision on Appeal dated April 25, 2003. More specifically, in that case, the Examiner’s rationale for the Section 112 rejection was as follows:

“The use of the terminology ‘adapted to’ makes the claim vague and indefinite because the scope of the claims cannot be ascertained, since it has been held the recitation that an element is ‘adapted to’ perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 U.S.P.Q. 138.

Decision on Appeal, p. 4. In reversing the Examiner’s claim rejections under 35 U.S.C. § 112, the Board noted:

“The use of the terminology ‘adapted to’ in claim 21 does not render claims 21-32 vague and indefinite since the scope of the claim can be ascertained. As set forth by the Examiner, the recitation that an element is ‘adapted to’ perform a function is a limitation which requires only that the structure be able to perform the function. As such, the scope of the claims can be ascertained with a reasonable degree of precision and predictability.

Decision on Appeal, pp. 4-5.

Accordingly, it is respectfully submitted that the language that the sharpened tip of the fracture pin is adapted to penetrate the subchondral bone is a positive limitation of the claimed invention and must be considered by the Examiner in determining patentability.

Having established that the limitation regarding the sharpened tip being adapted to penetrate subchondral bone is, in fact, a limitation of the present claims, it is respectfully submitted that Chanet does not anticipate the claimed invention. Chanet is directed to a device for tattooing animals, particularly piglets. Abstract; Col. 1, ll. 3-6. Chanet describes several problems with respect to the prior art devices for tattooing such animals, namely, problems associated with providing sufficient ink for the needles that will penetrate the skin of the animal. To that end, Chanet discloses a device comprising a plate 4 that carries a plurality of needles 41, and a pad 6. See Figure 2. Ink is supplied to the pad 6 via the coupling 74. Col. 4, ll. 4-5. In operation, the pad 6 is pressed against the skin of the animal to be tattooed, and the trigger 20 is squeezed to force the needles 41 through the pad 6 during which the entire surface of each needle becomes coated with ink. Col. 4, ll. 4-19.

As thus understood, it is respectfully submitted that Chanet does not anticipate independent claim 1. It is respectfully submitted that the needles 41 are not adapted to penetrate subchondral bone. The needles 41 in Chanet are merely adapted to penetrate, at least to some degree, the skin of an animal, namely a piglet. Accordingly, Chanet does not anticipate independent claim 1. Independent claims 15, 32 and 54 are likewise not anticipated by Chanet.

Having established that Chanet does not anticipate any of the pending claims, the next issue to be addressed is obviousness. However, it is respectfully submitted that Chanet is not analogous art to the present invention and cannot be employed as a reference in an obviousness analysis. "Two criteria have evolved for determining whether prior art is analogous: (1) [W]hether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the

reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved." *In re Clay*, 966 F.2d 656, 658-59 (Fed. Cir. 1992) (reversing Board holding of obviousness). "A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem. Thus, the purposes of both the inventor and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve. If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection. An inventor may well have been motivated to consider the reference when making his invention. If it is directed to a different purpose, the inventor would accordingly have less motivation or occasion to consider it." *In re Clay*, 966 F.2d 656, 659 (Fed. Cir. 1992) (reversing Board holding of obviousness).

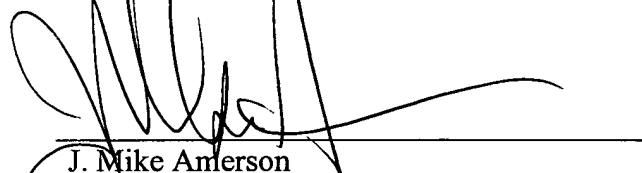
Applying these legal standards, it is respectfully submitted that Chanet is not analogous art for purposes of the present application. First, the device disclosed and claimed herein is directed to a medical device for performing an operation on a human. Moreover, as indicated in the claims, the sharpened tip of the fracture pin is adapted to penetrate subchondral bone. It is respectfully submitted that a device associated with mere tattooing is not within the field of endeavor of the present invention, nor reasonably related to a particular product to be solved by the present invention. It is respectfully submitted that a person skilled in the medical arts would not look to devices employed in tattooing for purposes of creating devices intended for intricate medical procedures on a subchondral bone of a human. Moreover, the act of tattooing is inherently a skin penetration process and would have little applicability to the area of a device adapted for penetrating a subchondral bone in a human.

On page 5 of the Office Action, the Examiner asked if independent claim 54 was intended to include any means-plus-functions limitations. Applicants hereby confirm that the limitation of "means for causing said sharpened tip to move and penetrate into said subchondral bone" in claim 54 is set forth in means-plus-function format. For the reasons set forth above, it is believed that independent claim 54, and all claims dependent therefrom are in condition for immediate allowance.

In view of the foregoing, it has been shown that Chanet does not anticipate the claimed invention and the Chanet reference is not analogous art as it relates to the claims pending in the present application. For at least these reasons, it is respectfully submitted that all claims pending in the present application are in condition for immediate allowance. The Examiner is invited to contact the undersigned attorney at (713) 934-4055 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

WILLIAMS, MORGAN & AMERSON  
CUSTOMER NO. 45488

A handwritten signature in black ink, appearing to read "J. Mike Amerson", is written over a horizontal line. The signature is fluid and cursive.

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J. Mike Amerson  
Reg. No. 35,426  
10333 Richmond, Suite 1100  
Houston, Texas 77042  
(713) 934-4056  
(713) 934-7011 (facsimile)

ATTORNEY FOR APPLICANTS